§ 520.1192 Ivermectin paste.

(a) Specifications. Each milligram (mg) of paste contains 0.0187 mg (1.87 percent) or 0.00153 mg (0.153 percent) of ivermectin.

(b) Sponsors. See sponsors in §510.600(c) of this chapter for use as in paragraph (e)(1) of this section:

(1) No. 050604 for use of a 1.87 percent paste as in (e)(1) of this section and a 0.153 percent paste for use as in paragraph (e)(2) of this section.

(2) Nos. 051311, 054925, 059130, and 061623 for use of a 1.87 percent paste for use as in paragraph (e)(1) of this section.

(c) Related tolerances. See §556.344 of this chapter.

(d) Special considerations. See §500.25 of this chapter.

(e) Conditions of use—(1) Horses—(i) Amount. 200 micrograms per kilogram (91 micrograms per pound) of body weight.

(ii) Indications for use. For treatment and control of Large Strongyles (adults); Strongylus vulgaris (also early forms in blood vessels), S. edentatus (also tissue stages), S. equinus, Triodontophorus spp. including T. brevicauda and T. serratus, and Craterostomum acuticaudatum; Small Strongyles (adults, including those resistant to some benzimidazole class compounds): Coronoclypus spp. including C. coronatus, C. labiatus, and C. labratus, Cyathostomum spp. including C. curtinatum and C. pateratum, Cyclicocyclus spp. including C. insignis, C. leptostrongylus, C. nasutus, and C. brevicapsulatus, Cylicodontophorus spp., Cyclicostephanus spp. including C. calcitatus, C. goldi, C. longibursatus, and C. minutus, and Petrovinema poculatum; Small Strongyles (fourth-stage larvae); Pinworms (adults and fourth-stage larvae): Oxyuris equi; Ascarids (adults and third- and fourth-stage larvae): Parascaris equorum; Hairworms (adults); Trichostrongylus axei; Large mouth Stomach Worms (adults): Habronema muscae; Bots (oral and gastric stages): Gasterophilus spp. including G. intestinalis and G. nasalis; Lungworms (adults and fourth-stage larvae): Dictyocaulus arnfieldi; Intestinal Threadworms (adults): Strongyloides westeri; Summer Sores caused by Habronema and Draschia spp. cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae, Onchocerca sp.

(iii) Limitations. For oral use only. Do not use in horses intended for human consumption.

(2) Cattle—(i) Amount. 23 milligrams per 250 pounds of body weight.

(ii) Indications for use. It is used in cattle for the treatment and control of gastrointestinal roundworms (adults and fourth-stage larvae) (Ostertagia ostertagi (including inhibited forms), O. lyrata, Haemonchus placei, Trichostrongylus axei, T. colubriformis, Cooperia oncophora, C. punctata, Nematodirus helvetianus, Bunostomum phlebotomum, Strongyloides papillosus (adults only), Oesophagostomum radiatum, Trichuris ovis (adults only)); lungworms (adults and fourth-stage larvae) (Dictyocaulus viviparus); grubs (first, second, and third instars) (Hypoderma bovis, H. lineatum); and sucking lice (Linognathus vituli, Haematopinus eurysternus).

(iii) Limitations. For oral use only. Do not treat cattle within 24 days of slaughter. Because withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age.

§ 520.1193 Ivermectin tablets and chewables.

(a) Specifications. (1) Each tablet or chewable contains 68, 136, or 272 micrograms (mcg) ivermectin.

(2) Each chewable contains 55 or 165 mcg ivermectin.

(b) Sponsors. See sponsors in §510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) No. 050604 for use of tablets or chewables described in paragraph (a)(1) as in paragraph (d)(1) and chewables described in paragraph (a)(2) as in paragraph (d)(2) of this section.

(2) Nos. 051311 and 059130 for use of tablets described in paragraph (a)(1) as in paragraph (d)(1) of this section.
§ 520.1195 Ivermectin liquid.

(a) Specifications.—(1) Each milliliter (mL) contains 10 milligrams (mg) ivermectin.

(2) Each mL of micellar solution contains 0.8 mg ivermectin.

(b) Sponsors.—See sponsor numbers in § 510.600(c) of this chapter.

§ 520.1194 Ivermectin meal.

(a) Specifications.—Each gram of meal contains 6 milligrams ivermectin (0.6 percent).

(b) Sponsor.—See No. 017135 in § 510.600(c) of this chapter.

(c) Special considerations.—See § 500.25 of this chapter.

(d) Conditions of use in horses.—(1) Amount. Administer 136 micrograms (mcg) ivermectin per pound (lb) body weight (300 mcg/kilogram) as a single dose on approximately 2 lb grain or sweet feed.

(2) Indications for use. For treatment and control of Large Strongyles (adults): Strongylus vulgaris; Strongylus edentatus (also early forms in blood vessels); S. equinus (also tissue stages); S. edentatus, Triodontophorus spp. including T. brevicauda and T. serratus, and Craterostomum acuticaudatum; Small Strongyles (adults, including those resistant to some benzimidazole class compounds): Coronocyclycus spp. including C. coronatus, C. labratus, Cyathostomum spp. including C. c tinatum and C. pateratum, Cylicocyclus spp. including C. insignis, C. leptostomum, C. nassatus, and C. brevicapsulatus, Cyclicodontophorus spp., Cyclicostephanus spp. including C. calicatus, C. goldi, C. longibursatus, and C. minutus, and Petrocinema pocalatum; Small Strongyles (fourth-stage larvae); Pinworms (adults and fourth-stage larvae): Oxyuris equi; Ascarids (adults and third- and fourth-stage larvae): Parascaris equorum; Hairworms (adults): Trichosptorynax azel; Large Mouth Stomach Worms (adults): Habronema muscae; Bots (oral and gastric stages): Gasterophilus spp. including G. intestinalis and G. nasalis; Lungworms (adults and fourth-stage larvae): Dictyocaulus arnfieldi; Intestinal Threadworms (adults): Strongyloides westeri; Summer Sores caused by Habronema and Draschia spp. cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae, Onchocerca spp. Limitations. Do not use in horses intended for human consumption.

[70 FR 1817, Jan. 11, 2005, as amended at 70 FR 19262, Apr. 13, 2005]

§ 520.1195 Ivermectin liquid.

Food and Drug Administration, HHS